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(71) Applicant (*for all designated States except US*): CAMP-
INA B.V. [NL/NL]; Hogeweg 9, NL-5301 LB Zaltbommel
(NL).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): ELLISON, Mark,
Jason, Heath [GB/NL]; Jan Heinstraat 2a, NL-5211 TD 's
Hertogenbosch (NL). LAMBREGTS-VAN DEN HURK,
Theodora, Antonia, Maria [NL/NL]; Generaal v. Vlij-
menstraat 5, NL-5463 CH Veghel (NL).

(74) Agent: VAN SOMEREN, Petronella, Francisca, Hen-
drika, Maria; Arnold & Siedsma, Sweelinckplein 1,
NL-2517 GK The Hague (NL).

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Published:

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*For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.*

(54) Title: EXCIPIENT FOR USE IN DRY POWDER INHALATION PREPARATIONS

(57) Abstract: The present invention relates to an excipient for dry powder inhalation preparations comprising granules made of primary carrier material, which granules break down during inhalation in such a manner that they give a concentration of primary carrier material at stage 2 of the twin stage impinger determined by the antrone reaction of at least 5%. Such excipients are for example obtainable by granulating a primary carrier material in a fluid binding agent and drying the granules thus obtained. The invention further relates to a method of preparing the excipient, to the use of the excipient and to dry powder inhalation preparations comprising the excipient.



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INTERNATIONAL SEARCH REPORT

International Application No.
PCT/EP 02/04207

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K9/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, WPI Data, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 750 492 A (GLAXO GROUP LTD) 2 January 1997 (1997-01-02) column 5, line 15-28; example 2 column 3, line 43-55, paragraph 15; claims 1-3	10-25, 27
A	WO 00 53157 A (MUSA ROSSELLA ; VENTURA PAOLO (IT); CHIESI PAOLO (IT); CHIESI FARMA) 14 September 2000 (2000-09-14) the whole document	10-27
A	US 5 738 865 A (STANIFORTH JOHN N ET AL) 14 April 1998 (1998-04-14) column 5, line 30-53 column 10, line 1-67; claims 1-5	10-27

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *S* document member of the same patent family

Date of the actual completion of the international search

28 January 2003

Date of mailing of the international search report

03/02/2003

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Uhl, M

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 02/04207

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 10-25, 27
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 10-25,27

Present claims 1-9, 26 relate to a product defined by reference to the following parameter(s):

"...break down in such a manner that they give a concentration of primary carrier material at stage 2 of the twin stage impinger determined by the antrone reaction of at least 5%"

The use of these parameters in the present context is considered to lead to a lack of clarity within the meaning of Article 6 PCT. It is impossible to compare the parameters the applicant has chosen to employ with what is set out in the prior art. The lack of clarity is such as to render a meaningful complete search impossible. Consequently, the search has been restricted to the subject matter of claims 10-25 and 27. Claims 1-9 and 26 furthermore relate to a product defined by reference to a desirable characteristic or property, namely that they break down in a certain manner during inhalation and determinable only by the twin stage impinger but to the in this connection unusual antrone reaction.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Application No

PCT/EP 02/04207

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